UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Technical Review Workgroup Bioavailability Committee
Dioxin/PAH Subcommittee
An interoffice workgroup convened by the Office of Superfund Remediation and Technology Innovation

Via e-mail

Date: May 19, 2015

Subject: Review of "Selection of the Relative Bioavailability Adjustment Factor for the Baseline Human Health Risk Assessment San Jacinto River Waste Pits Remedial Investigation/Feasibility Study CERCLA Docket No. 06-03-10"

From: EPA OSRTI Technical Review Workgroup Bioavailability Committee (TRW BAC) Dioxin/PAH Subcommittee

To: Gary Miller, Remedial Project Manager, US EPA Region 6

EPA Region 6 requested support from the EPA OSRTI Technical Review Workgroup Bioavailability Committee (TRW BAC) in the review of the "Selection of the Relative Bioavailability Adjustment Factor for the Baseline Human Health Risk Assessment San Jacinto River Waste Pits Remedial Investigation/Feasibility Study CERCLA Docket No. 06-03-10". If you have questions or would like clarification on the comments below, please feel free to contact us.

Baseline Human Health Risk Assessment (BHHRA) (page 5-15, paragraph 3): *An $RBA_{soil\text{-}sediment}$ of 0.50 was adopted for dioxins and furans. This value was derived from data on the bioavailability of TCDD in soils from a range of studies selected and presented by US EPA (2010d) in their Final Report on Bioavailability of Dioxins and Dioxin-Like Compounds in Soil. In their report, US EPA identified six studies that reported a total of 17 RBA test results for 2,3,7,8-TCDD in soil and sediment at concentrations ranging from 1.9 to 2,300 pg/kg. These studies reported bioavailability*

ranging from less than 0.01 to 0.49 (i.e., <1–49 percent). The arithmetic average of the mean bioavailability from each study was 0.23 (i.e., 23 percent). This value represents the "absorbed fraction from exposure medium on site" in Equation 5-5, above, and was divided by the assumed absorbed fraction of 0.50 (i.e., 50 percent) used in establishing toxicity criteria for DLCs adopted for this BHHRA (JECFA, 2002). The resulting $RBA_{soil\text{-}sediment}$ was 0.50, and this value was applied to calculation of exposures to all dioxin and furan congeners via incidental ingestion of soil and sediment. Given differences in the behavior of different DLCs in the environment, there is some uncertainty associated with the application of a value based on TCDD to all DLCs

Comment 1: The BHHRA used soil RBA estimates for TCDD measured at other locations (i.e., not the San Jacinto site) as a basis for deriving a soil RBA for PCDD/F congeners at the San Jacinto site. This approach is not appropriate (US EPA, 2010). Available data on RBA of PCDD/F in soil from other sites are not adequate to identify or derive a default RBA value of <1 (i.e., 100%) that can be generically applied to sites for the following reasons:

- a small number of soils have been assayed for PCDD/F RBA (8)
- the effect of congener chlorination on RBA is significant
- there are differences in RBA estimates based on swine and rat assays
- there is inadequate understanding of the soil properties that may affect congener RBA

As a consequence, the RBA adjustments to risk estimates made at any given site should be based on estimates of RBA made at that site and represent the congener mix and soils at that site. If this cannot be achieved, then the default assumption is that soil RBA is equal to one.

Comment 2: The BHHRA appears to have confused the concepts of RBA and ABA. The BHRRA selected a value 0.23 (23%) to represent the *"absorbed fraction from exposure medium on site"*. This value is presented as an estimate of ABA for TCDD and is used to derive a soil RBA for TCDD; however, it is actually an average of RBA (not ABA) for TCDD based on a subset of soils reported in US EPA 2010. ABA values are not reported in US EPA 2010 for reasons that are discussed in the report (the estimates would not be reliable without accounting for clearance). The basis for the estimate of 23% as an ABA for TCDD appears in a December 16, 2014 presentation prepared by Integral (*Relative Bioavailability Adjustment Factor for the San Jacinto River Waste Pits: Considerations Relevant to Site-Specific Evaluation*). Table 1 (page 13) of this presentation provides a summary of soil RBA values for TCDD selected from US EPA (2010) and reports a mean of 23% (Table 1 also summarizes congener mixture RBAs). Therefore, soil RBA applied to risk estimates at the site appears to be the ratio of $RBA_{soil/oil}/ABA_{food}$ for TCDD which does not provide an estimate of $RBA_{soil/food}$, as stated in the BHRRA.

Comment 3: The selection of soil RBAs for TCDD from US EPA (2010) is not appropriate in that it includes estimates from rodents given systemically toxic doses of TCDD (McConnel, 1984; Ubbriet, 1986; Wendling, 1989). These studies were excluded from consideration in US EPA (2010) because of concerns about the effect of toxicity on absorption and clearance. When all acceptable rodent studies reported in US EPA (2010) are considered, the average soil RBA for TCDD (relative to corn oil) is 40%, not 23% as reported in the HHRA.

Comment 4: Use of an estimate of soil RBA for TCDD to represent soil RBA for other congeners is not appropriate (US EPA, 2010). The BHRRA identified a value of 0.5 as ABA in rats administered TCDD in diet. The basis for this value is offered in a February 10, 2014 letter to Gary Miller (EPA Region 6) from Jennifer Sampson (Integral), which identifies Fries and Marrow (1975) as a source for the 0.5 value. Fries and Marrow (1975) was a study in which retention and elimination of TCDD was measured

in rats exposed to TCDD in the diet for a period of 42 days, followed by 28 days without exposure. Based on observed whole body retention (42 days) and elimination, the absorption fraction (ABA) was estimated to be 65% in male rats and 53% in female rats. The cumulative (42-day) doses of TCDD were approximately the rat LD_{50}; therefore, on that basis alone, the study is not considered to be appropriate for estimating ABA for applications to human health risk estimates (US EPA, 2010). Even if use of a study in which animals were dosed at or above the LD_{50} was determined to be appropriate in the BHRRA, the resulting ABA applies only to TCDD and cannot be used as a basis for estimating an RBA for any other congener. The analysis reported in US EPA (2010) shows that soil RBA varies with congener chlorine content, which suggests that values for TCDD should not be used to represent the soil RBA for other congeners.

References

Fries GF, Marrow GS. 1975. Retention and excretion of 2,3,7,8-Tatrachlorodibenzo-p-dioxin by rats. J. Agr. Food Chem. 23: 265-269

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